FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 7-8-9, 2001 Holiday Inn, Bethesda, Maryland

Draft AGENDA as of 2/27/01

<u>wednesday, March 7</u>							
8 AM		Session 1 - CLOSED SESSION					
9:15 Daum	, Committ	Begin Open Meeting ee Chair Call to Order, Introductions, Administrative Mai	Dr. Robert S.				
9:30		Open Public Hearing					
9:45	Biolog	Session 2 Open Session Infanrix _{DTPa} - HepB - IPV™ from SmithKline picals	<u>Beecham</u>				
FDA		Introduction	Dr. Rolf E. Taffs,				
	10:00 10:50	Sponsor's Presentation Questions on the Sponsor's Presentation					
11:10		Coffee Break					
	11:30	FDA Presentation 12:20 Questions on the FDA Presentation	Dr. Leslie Ball, FDA				
12:40		Lunch					
	1:35	Open Public Hearing					
	1:40 1:50	Presentation of Questions Committee Discussion					
3:30		Coffee Break					
3:50		Open Public Hearing					
	4:00	Committee Voting					
5:00		End of the Session; Adjourn for the Day					

FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 7-8-9, 2001 Holiday Inn, Bethesda, Maryland

DRAFT AGENDA as of 2/27/01

Thursday, March 8

ina on o							
Session 3 – CLOSED Session Session 4 – CLOSED Session Session 5 – CLOSED Session Session 6 – CLOSED Session							
Session 7 – Open Session –							
Developing New Pneumococcal Conjugate Vaccines for US Licensure							
Call to Order, Introductions, Announcements							
Introduction to the Topic Dr. Marior	1						
Dr. Carl	S						
Clarifications and Q&A							
Open Public Hearing							
Lunch							
Presentation of the Questions							
5 Committee Discussion							
Adjourn for the Day							
	Session 3 – CLOSED Session Session 4 – CLOSED Session Session 5 – CLOSED Session Session 6 – CLOSED Session Session 7 – Open Session – Developing New Pneumococcal Conjugate Vaccines for US Insure Call to Order, Introductions, Announcements Introduction to the Topic Dr. Marior Synopsis of the Workshop on Pneumococcal Conjugate Vaccine Dr. Carl Clarifications and Q&A Open Public Hearing Lunch Presentation of the Questions Committee Discussion						

FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

March 7-8-9, 2001 Holiday Inn, Bethesda, Maryland

DRAFT AGENDA as of 2/27/01

Friday, March	9
---------------	---

12:00

Triday, March 3							
8 AM		Call to Order, Introductions, Administrative Matters					
8:15		<u>Session 8 – Open Session</u> Completion of Formulation of Influenza Virus V	accine	for 2001-			
	<u>2002</u>						
Levan	8:15 dowski	Review of Current Situation	Dr. Ro	land			
	8:25	Additional information on Strain Surveillance and Epidemiology	Dr. Na	ncy Cox, CDC			
evan	8:40 dowski	Additional Information on	Dr. Ro	land			
	8:55	Serologic Results and Reference Strains Options for Strain Selection	Dr. Ro	land			
Levan	dowski	, FDA					
9:05	9:30	Coffee Break Committee Discussion and Voting					
10:00		Session 9 – Open Session Briefing on Activities in the Laboratories of Retrovirus Research and Immunoregulation					
	10:00	Introduction to the Laboratories and the Review	Proce	ss Dr. Peter			
Patria	rca, FD		1	D. H.			
Goldir	10:05 ng, FDA	Activities in the Laboratory of Retrovirus Resea	rcn	Dr. Hana			
	O .	Activities in the Laboratory of Immunoregulation A	1	Dr. Ira			
11:00		Session 10 - CLOSED Session					

End of session; Adjournment of the VRBPAC Meeting